

EXHIBIT 19

**To Plaintiffs' Memorandum Re
Relevancy and Discoverability of FDA
Inspection and Warning Letter and
Recovery Cone Removal System**

(part 3)

G. Recent Sample Article: Bariatric Surgery in General

04/11/2004 04:19:17

As Obesity Surgeries Soar, So Do Safety, Cost Concerns

Rob Stein, Washington Post Staff Writer

Source: *The Washington Post*

Date: April 11, 2004

Section: A Section

Page: A01

The number of overweight Americans resorting to stomach-shrinking surgery is rising so rapidly that health experts and insurance companies are increasingly becoming alarmed about the safety, effectiveness and mounting costs of the operations.

While the operations can produce dramatic benefits for very obese people, some hospitals and surgeons may be rushing too quickly to satisfy the surging demand, offering the lucrative procedures without adequate training, experience and support, experts say.

At the same time, the operations, which force people to eat less by reducing the size of their stomachs, are being performed too commonly on people who might be able to lose weight through diet and exercise, particularly younger adults and teenagers, they say.

Alarm has intensified because of scattered reports of severe complications and deaths around the country. In Massachusetts, for example, a special panel has begun assessing the procedure for state health authorities after several patients died following surgeries.

Citing uncertainty about the safety of the procedures and lingering questions about their long-term effectiveness, a growing number of insurance companies have begun balking at paying for the operations, which cost the nation close to \$3 billion a year.

To try to resolve some of these issues, the National Institutes of Health has launched a five-year, \$15 million research project to gather data about the operations, identify patients most likely to benefit and learn more about how they work.

In the meantime, the American Society for Bariatric Surgery, which represents surgeons who perform the procedures, has established an independent nonprofit corporation that in June will begin identifying "centers of excellence" deemed most qualified to do the complicated operations. The group is also gathering scientists at Georgetown University next month in the hopes of reaching a consensus on the risks and benefits of the treatment.

The rising concerns about stomach surgery illustrate the uncertainties that can occur with the emergence and proliferation of new surgical procedures, which often do not undergo the same level of testing, scrutiny and government oversight as new drugs or medical devices.

In addition, the debate over whether insurers should pay for the surgery illustrates the tension that is mounting as the obesity epidemic adds billions of dollars to the nation's medical bill. Millions of Americans already meet the criteria for the operation, which costs about \$25,000, and millions more are expected to join those ranks as obesity rates soar.

"Insurance companies are feeling the first pressure of the increasing costs of the rising obesity epidemic from this procedure," said Roland Sturm, who studies the economic impact of obesity for the Rand Corp., a private research organization. "If we look into the future, the rising obesity epidemic will continue to have tremendous effects on health care costs. It's an astonishingly big factor. And it's only going to get bigger."

As the number of obese Americans has soared and new, less invasive laparoscopic versions of stomach surgery have been introduced, the number of people undergoing the operations has skyrocketed, spurred by the lack of effective alternatives and by celebrity patients such as NBC's "Today" show weatherman Al Roker. The number of surgeries shot up from about 16,000 a year in the early 1990s to an estimated 103,000 in 2003 -- and is expected to approach 150,000 this year, making it one of the fastest-growing procedures. Many centers report long waiting lists.

Surgeons perform several variations, but all involve sharply restricting the size of the stomach, either by stapling most of it closed or sealing it off with elastic bands and bypassing portions of the digestive system to reduce the number of calories that can be absorbed. The procedures can enable severely obese people to lose hundreds of pounds, alleviating disabilities and preventing, even sometimes reversing, serious health problems, most notably diabetes and high blood pressure.

But the operations are complicated, and patients are prone to life-threatening complications, including bleeding, blood clots, leakages and infections. Even if they have no serious complications, patients often experience unpleasant side effects, including a phenomenon known as "dumping" -- nausea, vomiting and diarrhea -- when they overeat. As a result, patients have to undergo intensive counseling and monitoring to make sure they eat appropriately and do not suffer nutritional deficiencies.

"It's extremely difficult surgery," said Paul Ernsberger, an associate professor of nutrition at Case Western Reserve University. "Even when it's done perfectly, there can be a lot of problems."

According to federal guidelines issued in 1991, the procedure is supposed to be performed only on people who are at least 100 pounds overweight -- and primarily on those who are also suffering severe health problems because of their weight. While most people getting the procedure probably meet those criteria, there is concern that increasing numbers of people who weigh less are also undergoing the procedure.

"Many people who are not morbidly obese are trying to get this procedure. It's rapidly viewed as the answer to obesity, and more and more say, 'I can get surgery done as an answer to my problem,' " said Barry Schwartz of Blue Cross and Blue Shield of Florida. "We've actually seen a couple of patients who decided with their doctor that they would eat more so they could qualify. It's perverse."

Schwartz and other critics say the surge in popularity is enticing some hospitals and surgeons to try to capitalize on the interest.

"Many hospitals and physicians see this as a cash cow," Schwartz said. "We've seen surgeons who did a weekend course and then started doing this high-risk surgery. Make no mistake about this: This is high-risk surgery. The quality of service is going down, and the risk to patients is going up."

Some researchers also question the reliability of the data on the safety and effectiveness of the procedures.

"We don't have quality longer-term studies that give us good data on long-term safety and effectiveness," said Frank Lefevre, an associate professor of medicine at Northwestern University who evaluated the procedures for the Blue Cross and Blue Shield Association.

Already alarmed by skyrocketing health costs overall, a number of insurers, including Blue Cross and Blue Shield of Florida and Nebraska and Humana Inc., are discontinuing coverage for the operations.

"We've had an explosion in obesity and an explosion in the demand for quick fixes, if you will, to the problem of obesity," said Helen Darling, president of the National Business Group of Health, which represents major corporations on health issues. "It's beginning to dawn on insurance companies and employers that even after the surgery, there are a lot of big expenses and a lifetime of care. Many employers and insurance companies feel this is just not affordable today."

Some experts liken the situation to what happened with bone marrow transplants for breast cancer in the 1990s, when terminally ill breast cancer patients clamored for the procedure until carefully designed studies finally showed it did not save lives.

"Whenever a new technique seems to be providing benefit, it tends to proliferate," said Jonathan Moreno, a University of Virginia bioethicist who studies surgical procedures. "Oftentimes, these things gradually become the standard of care without going through any studies."

Proponents of the surgery say the procedures have undergone extensive study and have been clearly shown to help patients, enabling many to shed one-third to one-half of their excess body weight or more and keep it off for many years.

"I think these insurance companies may be using this as an excuse to avoid their responsibility. They think they can get away with this because of the prejudice that's out there for people who are obese," said Harvey Sugerman, president of the American Society for Bariatric Surgery. "I think it's a travesty."

For patients who have been suffering for years and been unable to lose weight despite repeated diets and exercise regimens, the operations are life-altering, he said. "It's an amazing operation. It's hard to describe how helpful it is to these patients. You have a patient who comes in who can hardly breathe, their legs are all swollen up, they have diabetes and high blood pressure, and they come back to you in three months, and they're all gone. They feel wonderful."

While the procedures can be dangerous, Sugerman and others said that for appropriate patients, the benefits clearly offset the risks, which are on a par with the dangers of operations for other life-threatening conditions involving seriously ill patients.

"It's actually surprising how good the results are," said David R. Flum, a University of Washington surgeon. "If you look at all the options available for the treatment of obesity, we know one thing for sure: Nonsurgical approaches, even the most radical approaches, even the most aggressive nonsurgical approaches, are horribly ineffective."

But Flum and some other experts acknowledge the complication rates are unclear. Most published studies have involved highly experienced surgeons operating on ideal candidates. Some research indicates the complication and mortality risks may be much higher than reported, especially as less experienced surgeons begin performing the procedures on a wider spectrum of patients.

"We really don't know what's happening in the real world, and there's a lot of reason to be really worried about that," said Flum, who is helping evaluate the procedures for the NIH consortium. "In the real world, surgeons may do many fewer patients per year. They are learning the procedure. Or picking patients who may not do as well. A lot of things have got us worried."

<http://www.washingtonpost.com>

[NA1]"MCVI" is the more commonly known name for the group of physicians in Miami of which Dr. Powell, the filter implanting physician, is a part.

[NA2]No. The number is not 6 now. This is the data that is in the product's package insert (IFU). These facts still hold for the Canadian cohort.

[NA3]I'm not sure which papers are being referenced here (the first and second papers, specifically)

[NA4]I think this entire 1st sub-bullet is problematic. We don't know how many filter have been implanted; we only know how many we've sold. Also, "success" really depends on how you look at it. Does lack of complaints equal success?

[NA5]An IVC filter does not prevent blood clots; it just keeps it from traveling to the lungs.

[NA6]Do we want to add that this was at post-mortem?

[NA7]Probably need to add additional comments about the initial conclusions of this incident.

[NA8]Probably need to add additional comments about the initial conclusions of this incident.

[NA9]Include that this was at post-mortem?

[NA10]Include that this was at post-mortem?

[NA11]Probably need to add additional comments about the initial conclusions of this incident.

[NA12]Although blood clots can originate in the arms, Recovery is not indicated for SVC use, therefore it does nothing to prevent PE from upper-extremity DVT (when used as labeled)

[NA13]Must stay away from calling all physicians "surgeons". The specialty with the largest proportion of IVC filter use is Interventional Radiologists. Filters are also used by cardiologists.

[NA14]Although blood clots can originate in the arms, Recovery is not indicated for SVC use, therefore it does nothing to prevent PE from upper-extremity DVT (when used as labeled)

[NA15]Must stay away from calling all physicians "surgeons". The specialty with the largest proportion of IVC filter use is Interventional Radiologists. Filters are also used by cardiologists.

[NA16]Although blood clots can originate in the arms, Recovery is not indicated for SVC use, therefore it does nothing to prevent PE from upper-extremity DVT (when used as labeled)

Internal Q&A: CR Bard Recovery Vena Cava Filter
Version May 10, 2004

Note: Internal Q&A to be used by approved Corporate spokespeople to respond consistently to inquiries from media. Not to be handed out externally to any audiences.

1. What is the Recovery Vena Cava Filter and how does it work?

Introduced in April 2003, the Recovery® Nitinol Vena Cava Filter is a blood clot trapping device designed to prevent pulmonary embolism by mechanical filtration. The filter is implanted percutaneously in the inferior vena cava (IVC). The Recovery Filter has the additional feature of being able to be percutaneously removed after implantation. The Recovery Filter may be used as a permanent or temporary device.

The Recovery Filter System consists of the Filter and Delivery System. The Filter consists of twelve nitinol wires emanating from a central sleeve. These twelve wires form two levels of filtration. The device is intended to be used in vena cava with diameters of up to 28 mm and is currently available for femoral vein approach only.

2. What is the difference between a retrievable vena cava filter and a non-retrievable vena cava filter?

A non-retrievable vena cava filter is indicated for permanent use; once inserted into the vena cava, the device is left in place. On the other hand, after implantation, a retrievable vena cava filter may be removed at the physician's discretion, usually once the risk of a venous thromboembolism or pulmonary embolism is reduced.

The Recovery Filter is designed to act as a permanent filter. When clinically indicated, the Recovery Filter may be percutaneously removed. The Recovery Filter's hooks allow the filter to remain rigid and provide anchoring, but deform when the filter apex is engaged with the specially designed removal device (Recovery Cone® Removal System) and pulled upward.

3. *What is the marketshare of the Recovery Filter for the overall vena cava filter market?*

6% (in units) .

4. *What is the marketshare of the Recovery Filter for the retrievable vena cava filter market?*

We have sold over 8,500 units of the Recovery Filter to date. We understand that the overall total market for all retrievable and non-retrievable vena cava filters is approximately 130,000 units.

While the retrievable segment of the vena cava filter market is rapidly growing, for the past 12-month period, the market is estimated to have been approximately 30,000 units. Of that, Recovery had a 25% share.

5. *How many Recovery Vena Cava Filters have been inserted in the US and, separately, around the world?*

[NAI] We have sold over 8,500 units of the Recovery Filter to date

6. *Do you have any studies that prove the safety and efficacy of the Recovery Vena Cava Filter?*

Yes. We have studies that prove the safety and efficacy of the Recovery Vena Cava Filter. For example, the Recovery Filter was safely and effectively used by an investigator and two colleagues at six Toronto area hospitals. In this Toronto study, of the 58 filters implanted, a total of 46 have been retrieved, 8 remain in place, and 4 patients have died with filters in place of causes unrelated to filter placement or retrieval.

In addition, the Recovery Filter underwent testing (bench top or animal studies or a combination of both) according to FDA guidelines to obtain FDA concurrence.

We are happy to provide a full listing of study summaries to you.

7. What are pulmonary emboli and what are the risks associated with them?

Pulmonary emboli are blood clots that form in large veins, such as those in the thigh, and then travel to the lungs. In the lungs, they block blood flow, which can cause shortness of breath, chest pain, faintness, low blood pressure, lung damage, and in severe cases, sudden death. Such clots are particularly likely to form in a variety of unusual circumstances, including prolonged immobility, after hip surgery, after major traumatic surgery and in obese individuals after weight reduction ("bariatric") surgery.

8. Under what circumstances would the Recovery Vena Cava Filter be used?

The Recovery Filter is indicated for use in the prevention of recurrent pulmonary embolism through permanent or temporary placement in the vena cava in the following situations:

- a. Pulmonary thromboembolism when anticoagulants are contraindicated.
- b. Failure of anticoagulant therapy for thromboembolic disease.
- c. Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- d. Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The device is intended to be used in vena cava with diameters of up to 28 mm, and when clinically indicated, the Recovery Filter may be percutaneously removed at the physician's discretion.

9. How is the Recovery Vena Cava Filter inserted?

The Recovery Vena Cava Filter is inserted into a femoral venous access route during a procedure performed by a medical professional. The "Instructions for Use" provide more information about the insertion and removal procedures.

10. Who designed the Recovery Filter?

Bard purchased the product design and manufacturing from a valued partner. Bard has thoroughly assessed and tested the product and stands behind its design in every way.

11. What is the name of the company that designed the Recovery Filter?

That information can be found in public records.

12. Have there been any design changes in the Recovery Filter over the years?

There have been changes in the delivery system but not the filter itself.

13. What level of expertise is required to properly insert the Recovery Vena Cava filter?

Physicians who have undergone training for minimally invasive, endovascular procedures can place the Recovery Vena Cava Filter. These physician specialties include, but are not limited to, interventional radiologists, vascular surgeons, trauma surgeons, cardiologists, and general surgeons as well as residents and fellows of those disciplines.

Placement of the Recovery Filter, in general, is quick (10 minutes) if there is easy access to the femoral vein. The procedure has been described by physicians as easy to perform.

14. How are doctors trained on the proper use of the Recovery Vena Cava filter? How extensive is this training?

There is currently no formal training requirement imposed on users by Bard for filter insertion.

Filter retrieval is under a limited market release process which requires the user to either 1) attend a one-day hands-on workshop or 2) have a qualified sales representative present for the initial three (3) cases.

15. What are the potential complications associated with the Recovery Vena Cava filter?

Potential complications observed for all types of inferior vena cava filters including the Recovery Filter include filter migration, perforation of the vena cava wall by filter legs, and vena caval occlusion or obstruction.

16. How often does the Recovery Filter actually migrate?

As of the end of April 2004, out of 8,500 devices sold in the U.S., there have been six reported cases of migration.

There is risk of migration with any vena cava filter. There is no single definitive cause of filter migration. The buildup of a large clot or series of clots, the movement of the walls of the vena cava due to respiration and improper filter placement can cause migration. There are also other factors that could potentially cause a filter to migrate, and many questions still remain as to exactly why filters migrate. In addition, filters may appear to have migrated due to x-ray equipment variation, patient position, measurement error, and respiration.

17. How does your rate of migration for the Recovery Filter compare to that of your retrievable and noretrievable device competitors?

Estimates based on available data suggest that these types of events are not occurring with excess frequency when compared with other vena cava filters.

18. Are retrievable filters more susceptible to migration than non-retrievable filters?

Estimates based on available data suggest that these types of events are not occurring with excess frequency when compared with other vena cava filters.

19. What causes filter migration?

Filter migration occurs whenever the force trying to move the filter exceeds the holding power of its fixation arms. A properly placed vena cava filter can constrain a significant amount of blood clot, but large blood clots can overwhelm the filter's retentive capabilities. Other recognized causes of filter migration include improper implantation technique, unusual patient exertion (such as straining at bowel movements) and fracture or failure of the filter wires. All marketed filters in the US have reported instances of filter migration. [NA3]

It also is important to point out that the exact reason/mechanism of filter migration has not been described in medical literature. In other words, no one knows for sure how/why filters migrate.

20. What is the "acceptable" rate of migration for vena cava filters?

Realistically, migrations do occur. All marketed filters in the US have reported instances of filter migration. Experts continue to debate what constitutes an acceptable rate of migration, relative to the risk of not using the filter.

21. What are the dangers associated with filter migration?

Most filter migrations are harmless to the patient and include filter movement of a few centimeters. In unusual cases, a filter containing a large amount of clot may migrate through the bloodstream to the lungs or heart. These complications can require surgical removal of the filter and clot, and rarely cause death. Without the filter, this amount of clot would generally have passed directly to the lungs or heart, causing substantial harm on its own.

22. If a retrievable filter provides the added benefit of retrievability and creates no greater risk of migration or other complications, why would any physician choose to use a non-retrievable filter?

I cannot speak on behalf of physicians but understand that non-retrievable filters can be less expensive than retrievable filters. Presumably, if a physician believes there will be no reason to remove the filter, it might make sense to choose the less expensive non-retrievable option. However, there is no way to predict with 100% accuracy whether or not a patient is going to require the filter for the rest of his/her life. I understand though, that an increasing number of physicians choose retrievable over non-retrievable vena cava devices after gaining greater understanding of the safety, efficacy and added benefits of retrievable filters.

23. Migration of a Recovery Filter was recently listed as the cause of death for a patient in Miami. Can you tell us why this specific filter migrated?

As with any report of an adverse event, we took an immediate, systematic approach to determine the cause and events. With this particular event, we formed a multi-disciplinary team to thoroughly investigate the incident. From the information available to date, no conclusions can yet be drawn regarding the role of the Recovery filter in this event.

We do know that there was a very large blood clot or an accumulation of blood clots, measuring 10 cm in length and 3 cm in diameter, which deposited around the filter over a period of several days. The large blood

clot or accumulated clots may have enveloped the filter and traveled through the bloodstream to the patient's heart, causing sudden death. The patient was morbidly obese but we are unsure whether this caused any health conditions. Morbid obesity can be the cause of blood clots.

24. If filter migration was not the cause of death, why was it listed as the cause of death on the coroner's report?

I cannot speak for the coroner. What I can tell you at this point, however, is that from the information available to date, no conclusions can yet be drawn regarding the role of the Recovery filter in this event.

We do know that there was a very large blood clot or an accumulation of blood clots, measuring 10 cm in length and 3 cm in diameter, which deposited around the filter over a period of several days. The large blood clot or accumulated clots may have enveloped the filter and traveled through the bloodstream to the patient's heart, causing sudden death. The patient was morbidly obese but we are unsure whether this caused any health conditions. Morbid obesity can be the cause of blood clots.

25. Is it possible that the filter was not inserted properly?

I do not want to speculate on the role of filter placement in this incident. What I can say is that, while improper filter insertion or placement can cause migration, we believe a blood clot as large as the one that enveloped the filter in this incident can very likely cause death.

26. Is there any reason to believe that the Recovery Filter is to blame for this patient's death?

I do not want to speculate on the role of the Recovery Filter in this incident. What I can say is that we believe a blood clot as large as the one that enveloped the filter in this incident can very likely cause death.

27. Has Bard been sued by the family of the deceased?

Not to my knowledge.

28. Has the Recovery Filter been associated with other deaths in the past?

Yes. A patient in Lacrosse, Wisconsin died with a Recovery Filter in place. The cause of death cited was pulmonary embolism.

29. Has Bard been sued because of death or damage caused by migration in the past?

Not to my knowledge.

30. In the late 80's, weren't Bard's balloon angioplasty medical devices permanently pulled from the market because of safety issues?

The Recovery Vena Cava Filter products we are discussing today are considered safe and effective by the medical community and had nothing to do with the situation you mentioned. In the late 1980s, a C.R. Bard subsidiary named USCI manufactured balloon angioplasty catheters, which were taken off the market. The details of criminal and civil lawsuits associated with these catheters are well documented. USCI was sold and no individual involved in those incidents is currently with the company. Since then, the entire executive management team has been changed. Today, Bard maintains an excellent working relationship with the FDA.

31. What other Bard products have been pulled from the market and for what reasons?

Bard has been in business for nearly a century, and we are known for our commitment to provide innovative, life-enhancing medical technologies to our patients. Holds can occur for a variety of safety and non-safety related reasons. In cases in which safety was a concern, products were placed back on the market after further testing. The Recovery Vena Cava Filter products we are discussing today are considered extremely safe and effective by the medical community.

32. What Bard products have been put on hold in the past two years?

As a course of company policy, we do not discuss previous product recalls. When such a recall occurs, we quickly and proactively provide necessary information to impacted customers, physicians and patients. The Recovery Vena Cava Filter products we are discussing today are considered safe and effective by the medical community.

33. Have you pulled any products over the past five years that have not been put back on the market? If yes, why were they pulled?

As a course of company policy, we do not discuss previous product recalls. When such a recall occurs, we quickly and proactively provide necessary information to impacted customers, physicians and patients. The Recovery Vena Cava Filter products we are discussing today are considered safe and effective by the medical community.

34. How does Bard receive and respond to reports of adverse events associated with its Recovery vena cava filter?

With any report of an adverse event, we take an immediate, systematic approach to thoroughly investigate the incident. Our system of tracking and monitoring complaints and adverse events enables us to respond directly to healthcare professionals. We take very seriously our responsibility of developing and delivering safe medical devices.

35. Are there any physicians I can talk with about the safety and efficacy of the Recovery Vena Cava Filter?

John A. Kaufman, MD [?]
Anthony C. Venbrux, MD [?]
Gary S. Cohen, MD
Thomas B. Kinney, MD
Christoph A. Binkert, MD
William S. Rilling, MD

36. Appropriate question must be developed and addressed regarding MAUDE database. Space holder question: Can you explain the data in the FDA's MAUDE database for the Recovery Filter as compared to other vena cava filters?

[PLEASE PROVIDE.]

[NA1]It is impossible to determine the number of filters that have actually been placed. The only data point that we can provide is the number that have been sold.

[NA2]Again, this is difficult to determine. All we know is how many have been sold. Also, does lack of complaints mean that it was safely used?

[NA3]It is important to point out that the exact reason/mechanism of filter migration has not been described in medical literature. In other words, no one knows for sure how/why filters migrate.

[NA4]This is not necessarily true.

External Q&A: CR Bard Recovery Vena Cava Filter
Version May 10, 2004

[Note: External Q&A are intended to be used by Bard Core and Audience Response Team members to consistently respond to questions from external audiences, and can be handed out to media, customers, physicians, suppliers, investors and other Bard audiences.]

1. What is the Recovery Vena Cava Filter and how does it work?

Introduced in April 2003, the Recovery® Nitinol Vena Cava Filter is a blood clot trapping device designed to prevent pulmonary embolism by mechanical filtration. The filter is implanted percutaneously in the inferior vena cava (IVC). The Recovery Filter has the additional feature of being able to be percutaneously removed after implantation. The Recovery Filter may be used as a permanent or temporary device.

The Recovery Filter System consists of the Filter and Delivery System. The Filter consists of twelve nitinol wires emanating from a central sleeve. These twelve wires form two levels of filtration. The device is intended to be used in vena cavae with diameters of up to 28 mm and is currently available for femoral vein approach only.

2. What is the difference between a retrievable vena cava filter and a non-retrievable vena cava filter?

A non-retrievable vena cava filter is indicated for permanent use; once inserted into the vena cava, the device is left in place. On the other hand, after implantation, a retrievable vena cava filter may be removed at the physician's discretion, usually once the risk of a venous thromboembolism or pulmonary embolism is reduced.

The Recovery Filter is designed to act as a permanent filter. When clinically indicated, the Recovery Filter may be percutaneously removed. The Recovery Filter's hooks allow the filter to remain rigid and provide anchoring, but deform when the filter apex is engaged with the specially designed removal device (Recovery Cone® Removal System) and pulled upward.

MAY. 11. 2004 2:15PM

CORP SA QA RA MA FAC

NO. 7782 P. 52

3. *How many Recovery Vena Cava Filters have been inserted in the US and, separately, around the world?*

We have sold over 8,500 units of the Recovery Filter to date

4. *Under what circumstances would the Recovery Vena Cava Filter be used?*

The Recovery Filter is indicated for use in the prevention of recurrent pulmonary embolism through permanent or temporary placement in the vena cava in the following situations:

- a. Pulmonary thromboembolism when anticoagulants are contraindicated.
- b. Failure of anticoagulant therapy for thromboembolic disease.
- c. Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- d. Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The device is intended to be used in vena cava with diameters of up to 28 mm, and when clinically indicated, the Recovery Filter may be percutaneously removed at the physician's discretion.

5. *Do you have any studies that prove the safety and efficacy of the Recovery Vena Cava Filter?*

Yes. We have studies that prove the safety and efficacy of the Recovery Vena Cava Filter. For example, the Recovery Filter was safely and effectively used by an investigator and two colleagues at six Toronto area hospitals. In this Toronto study, of the 58 filters implanted, a total of 46 have been retrieved, 8 remain in place, and 4 patients have died with filters in place of causes unrelated to filter placement or retrieval.

In addition, the Recovery Filter underwent testing (bench top or animal studies or a combination of both) according to FDA guidelines to obtain FDA concurrence.

We are happy to provide a full listing of study summaries to you.

6. What are pulmonary emboli?

Pulmonary emboli are blood clots that form in large veins, such as those in the thigh, and then travel to the lungs. In the lungs, they block blood flow, which can cause shortness of breath, chest pain, faintness, low blood pressure, lung damage, and in severe cases, sudden death. Such clots are particularly likely to form in a variety of unusual circumstances, including prolonged immobility, after hip surgery, after major traumatic surgery and in obese individuals after weight reduction ("bariatric") surgery.

7. How is the Recovery Vena Cava Filter inserted?

The Recovery Vena Cava Filter is inserted into a femoral venous access route during a procedure performed by a medical professional. The "Instructions for Use" provide more information about the insertion and removal procedures.

8. Have there been any design changes in the Recover Filter over the years?

There have been changes in the delivery system but not the filter itself.

9. How are medical professionals trained on the proper use of the Recovery Vena Cava filter?

There is currently no formal training requirement imposed on users by Bard for filter insertion.

Filter retrieval is under a limited market release process which requires the user to either 1) attend a one-day hands-on workshop or 2) have a qualified sales representative present for the initial three (3) cases.

10. Are there potential complications associated with vena cava filters?

Potential complications observed for all types of inferior vena cava filters including the Recovery Filter include filter migration, perforation of the vena cava wall by filter legs, and vena caval occlusion or obstruction.

11. What is the "acceptable" rate of migration for vena cava filters?

Realistically, migrations do occur. All marketed filters in the US have reported instances of filter migration. Experts continue to debate what constitutes an acceptable rate of migration, relative to the risk of not using the filter.

12. What causes filter migration?

Filter migration occurs whenever the force trying to move the filter exceeds the holding power of its fixation arms. A properly placed vena cava filter can constrain a significant amount of blood clot, but large blood clots can overwhelm the filter's retentive capabilities. Other recognized causes of filter migration include improper implantation technique, unusual patient exertion (such as straining at bowel movements) and fracture or failure of the filter wires. All marketed filters in the US have reported instances of filter migration. [NA2]

It also is important to point out that the exact reason/mechanism of filter migration has not been described in medical literature. In other words, no one knows for sure how/why filters migrate.

13. How does your rate of migration for the Recovery Filter compare to that of your retrievable and noretrievable device competitors?

Estimates based on available data suggest that these types of events are not occurring with excess frequency when compared with other vena cava filters.

14. Is CR Bard currently involved in any lawsuits surrounding the Recovery Vena Cava filter?

No

15. Has Bard been sued because of death or damage caused by migration of a Recovery Vena Cava Filter in the past?

No

16. How does Bard receive and respond to reports of adverse events associated with its Recovery vena cava filter?

With any report of an adverse event, we take an immediate, systematic approach to thoroughly investigate the incident. Our system of tracking and monitoring complaints and adverse events enables us to respond directly to healthcare professionals. We take very seriously our responsibility of developing and delivering safe medical devices.

17. Are there any physicians I can talk with about the safety and efficacy of the Recovery Vena Cava Filter?

John A. Kaufman, MD
Anthony C. Venbrux, MD
Gary S. Cohen, MD
Thomas B. Kinney, MD
Christoph A. Binkert, MD
William S. Rilling, MD

MAY. 11. 2004 2:16PM

CORR SA QA RA MA FAC

NO. 7782 P. 56

[NA1]Impossible to know how many have been placed. We have sold over 8500 as of the end of April.

[NA2]It is important to point out that the exact reason/mechanism of filter migration has not been described in medical literature. In other words, no one knows for sure how/why filters migrate.

[NA3]It is important to point out that the exact reason/mechanism of filter migration has not been described in medical literature. In other words, no one knows for sure how/why filters migrate.